

K113773

Section 4- 510(k) Summary

Submitter : St Jude Medical, CRMD
15900 Valley View Court
Sylmar, CA 91324
Establishment Registration Number: 2017865

JAN 18 2012

Contact Person : Geena George
Regulatory Affairs Specialist
Phone (818) 493 2629
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Date Prepared : December 21, 2011

Trade Name : St Jude Medical IS4 Flushing/Funneling tool Accessory kit
DS0A002

Classification : Class II – 21 CFR 870.1210
Continuous Flush Catheter

Product Code : KRA

Predicate Device: The subject device is equivalent to the following St Jude Medical
Device
IS4 Flushing/Funneling tool (approved under P030054/S173)

Device Description : The St. Jude Medical IS4 Flushing/funneling tool Accessory kit
Model DS0A002 is an individually packaged accessory kit
containing one IS4 flushing/funneling tool.

Intended Use: The IS4 Flushing/Funneling tool is to provide a means of flushing
the lead and facilitate the insertion of either a guidewire or stylet
into the connector pin of the over the wire left heart lead with an
IS4 connector.

Comparison to
Predicate Devices The St Jude Medical IS4 Flushing/Funneling tool Accessory kit
Model DS0A002 has an identical intended use and the same
fundamental scientific technology as the predicate device which is
commercially available.

Conclusion : St Jude Medical considers the IS4 Flushing/Funneling tool
Accessory kit Model DS0A002 to be equivalent to the predicate
device listed above. This conclusion is based upon the device
similarities in design, technological characteristics, principle of
operation, materials and indications for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JAN 18 2012

St. Jude Medical, CRMD
c/o Ms. Geena George
Regulatory Affairs Specialist
15900 Valley View Court
Sylmar, CA 91342

Re: K113773

Trade/Device Name: St. Jude Medical IS4 Flushing/Funneling Tool Accessory Kit
DS0A002

Regulation Number: 21 CFR 870.1210

Regulation Name: Continuous Flush Catheter

Regulatory Class: Class II (two)

Product Code: KRA

Dated: December 21, 2011

Received: December 22, 2011

Dear Ms. George:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

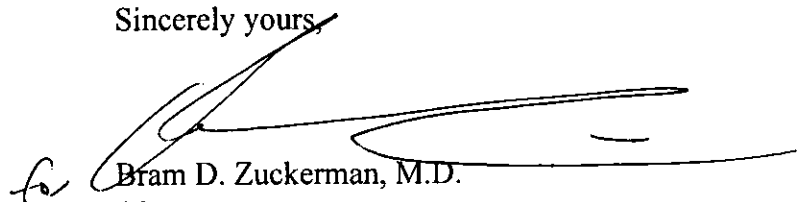
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a horizontal line.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use510(k) Number (if known): K113773Device Name: St Jude Medical IS4 Flushing/Funneling Tool Accessory kit Model
DS0A002

Indications for Use: The IS4 Flushing/Funneling Tool is to provide a means of flushing the lead and facilitate the insertion of either a guidewire or stylet into the connector pin of the over the wire left heart lead with an IS4 connector

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRA, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K113773